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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,659	11/25/2003	Peter James Dunn	PC10383B	8807
28523	7590	02/01/2005	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			MCKENZIE, THOMAS C	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/723,659	Applicant(s) DUNN ET AL.	
	Examiner Thomas McKenzie, Ph.D.	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-41 and 43-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-41 and 43 is/are rejected.
- 7) ☒ Claim(s) 44 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/886,269.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/25/03&11/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to amendments filed on 11/19/04. Applicant has amended claims 17, 26-29, 31, 35, 38, and 41. Applicant has canceled claim 42. Claims 17-41 and 43 were previously rejected. Claim 17-40, 44, and 45 were designated as containing allowable subject matter.

2. Because of the new indefiniteness rejection made to claim 29 concerning formula IV and VF, this action is being made non-Final.

Response to Amendment

3. Applicants' amendment concerning the priority overcomes the objection made in point #2 of the previous office action. Applicants addition of the structures of molecule VA overcomes the objection made in point #3 but has created a new indefiniteness rejection which is discussed below. Applicants addition of the needed formulas overcomes the objections made in points #4-#8. Applicants' deletion of "general" from the claims overcomes the indefiniteness rejection made in point #9. Applicants' new proviso in the sixth and seven lines below the formula in claim 41 overcomes the art rejection over Dunn (EP 812,845 A1, cited by Applicants) made in point #15. However, that proviso is new matter, which is discussed below. Applicants' listing of the possible carboxylic acid derivatives in claim 41 overcomes the art rejection over Johnson (Synlett) made in point #16.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-40 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Concerning formula II, in claim 26, Applicants have the limitation, "wherein R^X is a group substitutable by an aminopyrazole". In the passage spanning line 21, page 9 to line 11, page 10, Applicants provide an open definition of this term. In addition to the radicals listed in the passage discussed, what else is being claimed? The Examiner suggests either listing the claimed radicals or amending the specification to make clear what is being claimed.

Applicants correctly state that claim 17 has been amended to list the values of variable R^X . However, claim 26 still contains the functional definition.

5. Claims 17-25, 30, 31, and 41 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Concerning formula IV, Applicants have the limitation, "G represents *** or a derivative thereof." In the passage spanning line 21, page 11 to line 16, page 12, Applicants

provide an explanation, using open terms, of which derivatives they intended. In addition to the radicals listed in the passage discussed, what else is being claimed? The word "derivatives" is indefinite for we do not know which compounds are contemplated. A derivative is the result of a reaction upon an organic molecule. Since we do not know the reagents or the conditions of these reactions, there is no way of determining the structures of the claimed "derivatives". The phrase "derivatives thereof" is, in essence, a product by process claim. Yet Applicants have not described the intended processes sufficiently that we may understand the structures of the compounds they claim. Webster's New World Dictionary defines derivative as "a substance derived from ... another substance by chemical change", and "substitution of one or more elements or radicals for one or more constituents of the original substance" has occurred. All implying that new chemical bonds have formed. The Examiner suggests either listing the claimed derivatives or amending the specification to make clear what is being claimed.

Applicants point to the paragraph spanning pages 11-12 as defining the phrase " derivative of a carboxylic acid". This is not persuasive because the passage to which Applicants' point contains the open terms "includes" and "can also represent". In addition to the derivates contained in the passage under discussion what other derivates are being claimed? Where applicant acts as his or

her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

6. Claims 17-25 and 30-37 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the final two lines of claim 17, Applicants have the limitation, "with an appropriate reagent for converting the group G to a $-C(RX)=NH$ group". In the passage spanning line 17, page 12 to line 4, page 16, Applicants give examples of such reagents using the open term "for example". In addition to the reagents listed in the passage discussed, what else is being claimed? The Examiner suggests either listing the claimed radicals or amending the specification to make clear what is being claimed.

Applicants argue that the passage discussed above defines the structure of the "appropriate reagent". This is not persuasive because the passage to which Applicants' point contains the open term "for example". In addition to the reagents

contained in the passage under discussion what other reagents are being claimed? Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

7. Claims 26-29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the final line of claim 26, Applicants have the limitation, "with a reagent that will convert one RX group to another". In the passage spanning line 6, page 16 to line 14, page 17, Applicants give examples of such reagents using the open term "for example". In addition to the reagents listed in the passage discussed, what else is being claimed? The Examiner suggests either listing the claimed radicals or amending the specification to make clear what is being claimed.

Applicants argue that the passage under discussion defines the phrase and offer reagents VA, VD, and VF as examples of such reagents. This is not persuasive because the passage to which Applicants' point contains the open term

"for example". In addition to the reagents VA, VD, and VF contained in the passage under discussion what other reagents are being claimed? Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

8. Claim 27 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While variable R^{α} is defined in claim 17, part (b), it is not defined in independent claim 26, upon which claim 27 depends. The Examiner suggests using the definition from claim 17.

9. Claim 29 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There are two issues. Firstly, formula IV, while defined in claim 17, it is not defined in independent claim 26, upon which claim 29 depends. The Examiner suggests using the definition of formula IV from claim 17. Secondly, the two occurrences of the formula "VF" appear to be

superfluous. The Examiner suggests removing both so claim 29 reads "-SH is reacted with a compound of formula R^d-Z^2 wherein", if that is what is intended.

10. Claim 31 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the final line of the claim, "with a reagent that may be used for the introduction of a SO_2L^1 group into an aromatic or heteroaromatic ring system". In the passage spanning line 19, page 18 to line 25, page 18, Applicants give examples of such reagents using the open term "for example". In addition to the reagents listed in the passage discussed, what else is being claimed? The Examiner suggests either listing the claimed radicals or amending the specification to make clear what is being claimed.

Applicants argue that a single method of introducing SO_2L^1 group into an aromatic ring is provided in the specification and that the skilled organic chemist would understand what other reagents are suitable for this purpose. This is not persuasive. The chemist making Applicants compounds would be a process chemist or pilot plant operator with a BS degree in chemistry and several years of experience. He would know how to use SO_2Cl_2 to affect this process, since such a reaction is found in his organic chemistry textbook but be unaware of other

reagents suitable for this purpose since no other such procedures are normally taught during undergraduate chemistry training.

11. Claim 43 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 43 recites the limitation "G represents CO₂Et" in line 2. There is no antecedent basis for this limitation in the parent claim 41, which does not allow G to be an ester group.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to convey reasonably to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The two provisos in sixth and seven lines below the formula in claim 41 and in the last three lines of the claim lack description. Nowhere in the specification is such a relationship linking the description among radicals A, G, R³ and R⁴ described. Such negative limitations require description. In *Ex parte Grasselli, et al.* 231 USPQ 393, decided June 30,

1983, the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences said: "we agree with the examiner's position of record that the negative limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112." "It might be added that the express exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts."

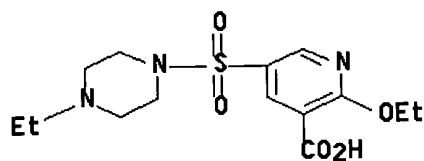
Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41 and 43 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bunnage (WO 99/54333 A1). The compound shown below fits formula (IV) with $A = N$, $R^3 = R^4 = \text{ethyl}$, and $G = \text{CO}_2\text{H}$. It has registry number 247582-73-6 and is found in lines 11-26, page 126 of the reference. It is called Preparation 23. The ethyl ester is found in the passage spanning line 11, page 123 to page 124. Thus, claim 43 is anticipated. Unfortunately, page 124 is missing from the Examiner's copy of this reference.



Applicants argue that the compound taught in the reference is not an ethyl ether as depicted about but rather is an ethoxyethyl ether. The compound to which the Examiner originally pointed on lines 10-24, page 127 is an ethoxyethyl ether. However, the compound on page 126 is an ethyl ether as pictured above by Chemical Abstracts. The missing page 124 may have caused the confusion in the page numbering.

Allowable Subject Matter


14. Claims 44 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 17-40 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (571) 273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 9:00am to 5:30pm, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.


Thomas C. McKenzie, Ph.D.
Primary Examiner
Art Unit 1624

TCMcK/me